Table 2

Author, date and country	*Patient group*	*Study level*	*Outcomes*	*Key results*	*Study weaknesses*
Hull RD, *et al*, 1992, USA[1]	432 patients with proximal DVT UH (219) *v* LMWH (213)	Multi-centre randomised double blind clinical trial	Recurrence of VTE	6/213 *v* 15/219 (p=0.07; 95% CI for the difference, 0.02% to 8.1%).	
			Major bleeding	1/213 patients (0.5%) *v* 11/219 (5%), reduction in risk of 91% (p=0.006).	
			Death	10/213 (4.7%) *v* 21/219 (9.6%) a risk reduction of 51% (p=0.049).	
Koopman MM, *et al*, 1996, Multi national[2]	400 patients with symptomatic proximal deep vein thrombosis UH in hospital (198) LMWH at home (202)	PRCT	Recurrent VTE (within 6 months)	17/198(8.6%) *v* 14/202 (6.9%).	Unblinded
			Major bleeding (within 3 months)	4/198 *v* 1/202.	
			Quality of life (at 1, 12 and 24 weeks)	Physical activity and social functioning better in LMWH group.	
			Average length of stay	In the LMWH group was 2.7 days *v* 8.1 in the UH group.	
Levine M, *et al*, 1996, Canada[3]	500 patients with acute proximal deep vein thrombosis UH in hospital (253) *v* LMWH primarily at home (247)	PRCT	Recurrent VTE	17/253 (6.7%) *v* 13/247 (5.3%).	Two thirds of potential patients excluded
			Major bleeding	3/253 (2%) *v* 5/247 (2%).	
			Costs	6.5 days in hospital *v* 1.1 days. 120 (49%) patients in LWMH were not admitted at all.	
Belcaro G, *et al*, 1999, Italy[4]	294/589 patients with acute proximal UH in hospital (98) *v* treatment with LMWH primarily at home or in the hospital (97) *v* treatment with SCHep given directly at home (99)	PRCT	Recurrence/extension of DVT	6.2% *v* 6.1% *v* 7.1%.	264 (44%) of potential patients excluded
			Bleeding	Bleeds were all minor and mostly during hospital stay	
			Length of stay	5.4 ± 1.2 *v* 1.2 ± 1.4 days (there was no hospital stay in the SCHep group)	
			Treatment costs	Average treatment costs in 3 months in the UH group were considered to be 100%. In comparison costs in the LMWH group was 28% of the UH and 8% in the SCHep group	

1 Hull R, Raskob G, Pineo G, *et al*. Subcutaneous low weight molecular weight heparin compared with continuous intravenous heparin in the treatment of proximal vein thrombosis. *N Engl J Med* 1992;**326**:975–82.
2 Koopman M, Prandoni P, Piovella F, *et al*. Treatment of venous thrombosis with intravenous unfractionated heparin administered in the hospital as compared with subcutaneous low molecular weight heparin administered at home. *N Engl J Med* 1996;**334**:682–7.
3 Levine M, Gent M, Hirsh J, *et al*. A comparison of low molecular weight heparin administered primarily at home with unfractionated heparin administered in the hospital for proximal vein thrombosis. *N Engl J Med* 1996;**334**:677–81.
4 Belcaro G, Nicolaides A, Cesarone M, *et al*. Comparison of low molecular weight heparin, administered primarily at home, with unfractionated heparin, administered in hospital and subcutaneous heparin administered at home for deep vein thrombosis. *Angiology* 1999;**50**:781–7.

Outpatient treatment for patients with uncomplicated above knee deep vein thrombosis

Report by Beverley Lane, *Research Nurse*
Search checked by Magnus Harrison *Clinical Research Fellow*

Clinical scenario
A 25 year old man presents at the emergency department with a two day history of a swollen and painful right leg. A DVT is suspected and an ultrasound confirms the presence of an extensive clot in the femoral vein. Otherwise he is fit and well. There are no beds in the hospital and you wonder whether the evidence exists to confirm that this patient can be treated safely as an outpatient using low molecular weight heparin.

Three part question
In [patients with an above knee uncomplicated DVT] is [outpatient management with low molecular weight heparin or traditional inpatient management] [feasible and safer]?

Search strategy
Medline 1966–07/00 using the OVID interface. {(Exp venous thrombosis OR deep vein thrombosis.mp OR dvt.mp) OR [(exp thrombosis OR exp venous thrombosis OR thrombosis.mp) AND (exp veins OR Vein$.mp OR vein$.mp)] AND (exp hospitilization OR hospitalisation.mp) OR (inpatient.mp) OR (outpatient.mp OR exp ambulatory care OR ambulatory care.mp) AND (exp heparin OR exp heparin, low molecular weight OR heparin.mp OR exp anticoagulants OR anticoagulants.mp NOT prophylaxis.mp OR exp primary prevention OR prevention.mp)] AND (exp therapeutics OR treatment.mp). LIMIT to human AND english language.

Search outcome
Altogether 493 papers identified of which 485 were irrelevant or of insufficient quality for inclusion. The remaining eight papers are shown in the table 3.

Comments
There are no randomised control trials to answer the question posed. However, all the cohort studies come to the same conclusion.

Clinical bottom line
Selected patients with uncomplicated proximal DVT can be treated safely as outpatients.

Table 3

Author, date and country	*Patient group*	*Study level*	*Outcomes*	*Key results*	*Study weakness*
Lindmarker P and Holmstrom M, 1996, Sweden[1]	434 patients with symptomatic DVT, 239 proximal, 195 distal Patients were followed up for 3 months	Cohort	Recurrent DVT, incidence of pulmonary embolus, bleeding events, death	Frequency of major events during the administration of LMWH was 0.92% with an exact 95% CI of 0.25, 2.35% During the 3 month follow up period there were 3 reoccurrences and 1 PE There were no deaths during initial treatment with LMWH	High incidence of distal DVT (45%) may have affected the complication rate
Mattiasson I, *et al*, 1997, Sweden[2]	523 consecutive patients from 6 hospitals Patients followed up for 3 months	Cohort	Any bleeding event, pulmonary embolus (PE), progression of thrombus Eligibility	No serious bleeding event was reported. No serious thromboembolic complication was noted. 197/523 (38%) were deemed suitable (according to criteria) for total outpatient care 43 (8%) were initially hospitalised but then discharged after a median of 2 days	Excluded patients with thrombus involving the v iliaca and v cava This may reflect the zero incidence of PE
Grau E, *et al*, 1998, Spain[3]	71 consecutive patients presenting to the ED with a DVT (56 proximal, 15 calf) Patients were assessed monthly for 6 months	Cohort	Recurrent venous thromboembolic event (VTE) Ambulatory care	No patients had VTE recurrence during the 6 months of follow up. Ambulatory care was feasible in 39 (55%) of patients. 24 of these were not hospitalised at all and the remaining 15 were discharged within 2 days	Small number of patients
Groce B, 1998, USA[4]	125/142 patients with acute proximal DVT	Cohort	Length of stay Recurrent DVT Bleeding	From 5.4 to 0.97 days. 84 patients were in hospital ≤24 hours. The remaining 41 stayed between 1.1 and 3 days 1/125 In 2/125	Preliminary results
Harrison L, *et al*, 1998, Canada[5]	89/113 consecutive patients 69 had proximal DVT, 11 calf vein DVT, 7 had upper extremity DVT, 2 had PE Patients were followed up at 3 months after initial diagnosis	Cohort	Bleeding episode Recurrent VTE Patient satisfaction	There was 1 bleeding episode requiring admission 5 cases of recurrent VTE were reported (all had malignant disease) 1 death was reported 75/82 (91%) were pleased at home treatment	Some patients were followed up at 3 months over the telephone, which may affect validity of findings Possibility that satisfaction questionnaire not validated
Ting S, *et al*, 1998, Australia[6]	100 consecutive patients with acute lower limb DVT (53 proximal, distal 47) Patients were followed up for 6 months	Cohort	Bleeding Recurrent VTE PE	6 minor bleeding complications. In 2 of these Dalteparin was stopped 4 patients had reoccurrence between 5–12 months No episodes of symptomatic PE reported	
Wells P, *et al*, 1998, USA[7]	194/233 patients presenting with DVT were recruited into 2 care models Patients were followed up for 6 months	Cohort	Recurrent VTE Bleeding events	The overall recurrent event rate was 3.6% (95% CI 1.5%, 7.4%) The overall rate of major haemorrahge was 2.0% (95% CI 0.6%, 5.2%) More than 184/194 patients were treated mainly at home	As patients were cared for in a highly supervised research setting, evidence of their satisfaction/anxiety with the service could have been assessed
Yusen D, *et al*, 1999, USA[8]	195 hospitalised patients diagnosed as having a proximal DVT were assessed for outpatient treatment.	Cohort	Recurrent VTE, major bleeding, death Eligibility	No complications were recorded in any of the 36 eligible or possibly eligible patients Of the 159 patients classified as ineligible, 13 (8%; 95% CI 4%, 12%) died or developed serious complications	Criteria applied retrospectively Lack of documentation may have limited the ability to determine accurate complication rates

1 Lindmarker P, Holmstrom M. Use of low molecular weight heparin (Dalteparin), once daily for the treatment of deep vein thrombosis. A feasibility and health economic study in an outpatient setting. *J Intern Med* 1996;**240**:395–401.
2 Mattiasson I, Berntorp S, Bornhov S, *et al*. Out patient treatment of acute deep vein thrombosis. *Int Angiol* 1998;**17**:146–50.
3 Grau E, Real E, Pastor E, *et al*. Home treatment of deep vein thrombosis: a two years experience of a single institution. *Haematologica* 1998;**83**:438–41.
4 Groce J. Patient outcomes and cost analysis associated with an outpatient deep vein thrombosis treatment program. *Pharmacotherapy* 1998;**18**:175–80S.
5 Harrison L, McGinnis J, Crowther N, *et al*. *Arch Intern Med* 1998;**158**:2001–3.
6 Ting S, Ziegenbein R, Gan TE, *et al*. Dalteparin for deep vein thrombosis: a hospital in the home programme. *Med J Aust* 1998;**168**:272–6.
7 Wells P, Kovacs M, Boramis J, *et al*. Expanding eligibility for outpatient treatment of deep vein thrombosis and pulmonary embolism with low molecular weight heparin. A comparison of patient self-injecting with homecare injection. *Arch Intern Med* 1998;**158**:1809–12.
8 Yusen R, Haraden B, Gage B, *et al*. Criteria for outpatient management of proximal lower extremity deep vein thrombosis. *Chest* 1999;**115**:972–9.

SimpliRed D-dimer assay in suspected pulmonary embolus

Report by Magnus Harrison, *Research Fellow*
Search checked by Steve Jones, *Research Fellow*

Clinical scenario

A 40 year old man presents with acute suspected pulmonary embolus (PE). You wonder whether a negative SimpliRed D-dimer assay is sufficient to rule out the diagnosis of PE.

Three part question

In [a patient suspected of having an acute pulmonary embolus] is [a negative SimpliRed d-dimer assay] able to [rule out PE]?